

Milner, John A. 2008

Dr. John A. Milner Oral History 2008

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National Cancer Institute

Division of Cancer Prevention Oral History Project Interview with John A. Milner

Conducted on December 11, 2008, by Philip L. Cantelon

Dr. John Austin Milner currently serves as Chief of the Nutritional Science Research Group, Division of Cancer Prevention, National Cancer Institute. A native of Pine Bluff Arkansas, Dr. Milner received his Bachelors of Science degree in 1969 from Oklahoma State University. In 1974 he completed his PhD at Cornell University with a major in nutrition and a minor in biochemistry and physiology. From 1989 to 2000, Dr. Milner served as the Head of the Department of Nutrition and the Director of the Graduate Program in Nutrition at Pennsylvania State University. In 1999 he joined the Nutritional Science Research Group at the Division of

Cancer Prevention and became the Chief of this research group in 2000. Dr. Milner is a member of the American Society for Nutrition, American Association of Cancer Research, American Chemical Society's Food and Chemistry Division, the Institute of Food Technology and the International Society of Nutrigenetics/Nutrigenomics.

This interview covers Dr. Milner's arrival at the Division of Cancer Prevention and his contributions to the development of nutritional sciences. It touches on the history of nutrition research and cancer, coordination with the scientific community, and evolution of the Nutritional Science Research Group. He discusses the Women's Intervention Nutrition Study and the variety of compounds research by the division.

PC: I am speaking with Dr. John A. Milner, that's M-I-L-N-E-R, on December 11th, 2008, and I have your permission to record the call?

JM: You certainly do.

PC: Thank you. Let me start this morning with a couple of things about you personally.

JM: Okay.

PC: You got into nutrition really at Cornell?

JM: Well, actually, I would say I got in about – at Oklahoma State University. I was a work study student there. Initially I got involved in some nutrition projects, and that's what pushed me into graduate school at Cornell.

PC: What – what's the journey between going into nutrition and the linkages between nutrition and cancer?

JM: For about the last 35 years, we've been thinking that about a third of all cancers relate to dietary habits. It actually surfaced from a study from Doll and Peto that occurred almost 35 years ago. It suggested that about a third of cancers related to smoking habits and about a third related to dietary habits, and then a third believed to – some other environmental factor. To date I think, a wealth of evidence points to a number of foods and food components that are associated with the incidence and behavior of tumors.

Clearly there is a lot more evidence in pre-clinical models than we have with clinical models. You know, we don't all eat the same thing, and our genetics are a little different, all of those things make for important variables, and that's the reason it's 30 percent, 35 percent, and not higher.

PC: And what – so 35 years ago, I'm trying to – I have to – trying to do my math and calculate that, but let's say it was 19 –

JM: I mean, it doesn't matter. Around the 1970s –

PC: Seventies?

JM: — is roughly when this occurred, so yeah.

PC: As I recall, in the late 70s, the Surgeon General came out with a report on health and prevention.

JM: That's correct, diet and health. It, along with several other documents pointed to diet as an important variable in determining health and disease prevention.

PC: And did that have an impact on people? By that time, I guess, you were at Illinois?

JM: Uh-huh. Absolutely. You know, there were a couple of reports that came out. In fact, there was even one from the World Cancer Research Fund that suggested that diet was very important. But the Surgeon General's report was very instrumental in setting the tone across many academic institutions and industry for how we improve human health. Undeniably, it fostered some fundamental and transitional research. It's still – in many ways, it's – I don't know, I'm not quite sure what to say, I guess I'll say candidly everybody eats, and everybody thinks that they know the definition of what is an ideal diet, but we haven't really defined it for large groups and much less for individuals.

Probably, ideal depends on the individual and the circumstances. So it's made it very difficult to identify one ideal diet. In fact, if there is such a thing, I'm not sure there would be that many people that would eat it!

PC: [Laughter]. In other words, it's not a model for a fast food business?

JM: That's correct. You know, I think there are a number of issues that must be considered when it comes to diet. I think eating is actually still one of the pleasures of life, and it's more than just nourishment. There's a lot of things that do happen. So you have to balance all of these things that are going on. There are potentially strategies – I think they're more than potential, there are strategies for minimizing your risk. The major killers – you know, the Surgeon General's report, the one you're talking about in the 70s suggested that five of the ten leading causes of deaths of Americans relate to dietary habits. And the two major killers, as you know, are heart disease and cancer, and both of those are related to dietary habits.

PC: Uh-huh. And yet, over the years, we get conflicting – or changing, I suppose, views of what are good and bad for us.

JM: Yeah, I think a lot of that comes down to the science we're trying to promote in the Division of Cancer Prevention in an attempt to get the best evidence we can to deal with nutrition science more than observational evidence that is in the literature. I refer to it at times a "cook and look". A lot of it is guilt by association. You know, we do an epidemiological study, which is okay by itself, but yet if you don't have a good assessment of what people are truly eating and the environmental factors that go along with that, physiological factors that go along with that, you really don't know how to interpret the data. We have major problems when it comes to assessing eating behaviors of people. We haven't really been thinking in terms of some of these nutrients having a site of action and the interaction among nutrients at that site of action. For the last, oh, ten years at least, we've been talking a lot more about genomics and how individuality sets the tone for the response. It has not been really adequately examined when it comes to how diet plays a role in the response to foods or its components. So this whole topic of nutrigenomics, I think, is incredibly important. In the future these investigations will help us understand why there is so much variability in the literature and thus among individuals in the benefits or risks that are observed.

PC: So much what in the literature? I missed that.

JM: Variability.

PC: Variability. Okay.

JM: Right. There is a mindset, which I've always argued is wrong, that all people respond identically. In fact, I think you're well aware of friends who can eat the same thing and they will be lean, and others that will be obese. We have circumstances in which some foods people like, and others don't. We're not all the same. We don't all respond the same. And we're finding more and more cases now of how genes can set the tone for what we like to eat, what's absorbed and how it functions once it's in the body proper.

PC: Let me ask you, what encouraged you to come to NIH in the late 90s?

JM: [Laughter]. That's an interesting question. I had been department head at Penn State for a number of years, about twelve years, in fact, and I thought it was time for a change.

You can talk to some of the faculty. They thought it was beyond time for a change [laughter].

PC: [Laughter]. That's the risk of being an administrator.

JM: That's right. But, you know, most of us didn't last more than five years, and so to last that long was quite an accomplishment, as far as I was concerned. But, honestly, I wanted to learn a little bit more about the NIH system. I had NIH grants but did not know enough about the overall grants process. I had a friend-colleague who was here in the division, Dr. Carolyn Clifford.

PC: Yeah.

JM: Carolyn and I were friends/colleagues back in Oklahoma, in fact. So we had a long history of knowing each other and working together. So I said, "Well, it would be kind of fun to come here and learn a little bit more about this nutrition at NIH, and then go back and be a real scientist at Penn State." I was here for, I don't know, probably three or four months, and Dr. Greenwald asked me to be Acting Chief of the Nutritional Science Research Group. I then knew then that I was doomed to administration, so I said okay.

Actually, I really started enjoying it. I thought that I could make a difference here because I have spent so long in academia. So I saw it more as a challenge and opportunity, and took it.

PC: Now when you became acting chief, this is of the nutrition science research group.

JM: Right.

PC: Were you on an IPA then or –

JM: I was. It was a very interesting time because I was a non-federal employee. I couldn't sign off on some items, but yet, I was still the chief [laughter], so – or acting chief. So, you know, it was really much more what Peter, I think, was looking for, creativity and for us to be proactive. I have, over the years, developed a number of contacts, both in this country and abroad. He wanted to build my background and experiences and I think we have done that. We've been very successful in getting additional grantees supported.

We've been creative, kind of dynamic and helped the nutrition community. It wouldn't have happened without Peter, I might add.

PC: Well, let me ask. So he actually recruited you after you came. He did not know you were – know you well.

JM: I knew Peter, but not well. And so, absolutely. That's after the fact he recruited me.

PC: Dietary issues have always raised a good deal of controversy in the 80s and 90s, both outside and inside the NIH. What was the situation you found by the 1990s?

JM: I, actually, found this an incredibly conservative group that was not necessarily willing to push the envelope to really find out what's going on. I'm much more keen on talking about functional foods, meaning foods that have some health benefit over and beyond basic nutrition. I'm much more receptive to talking about bioactive food components, and I would say one of the things that's happened over the last eight years is that we have embraced the "omics" technologies because I really was concerned about a lot of the variability that was occurring in the literature and trying to understand why it was occurring. We spend a lot of time talking about molecular targets, etcetera. It's almost a drug paradigm when it comes to nutrition, and I think sites of action and molecular approaches are what we need to think about. You know, it's back to my statement earlier that not all people are going to respond the same way, and we need to understand who is going to respond and under what circumstances. Again that response could be either positive or negative.

So it's a very interesting issue that has surfaced. I'd like for nutrition to surface as being very important, but I think what's really most important is that we have the solid science to say one way or the other. And so that's what we're really after, within the Nutritional Science Research Group.

PC: And before you got there, what was the focus?

JM: Well, I think it was more dietary patterns. We had a relatively small portfolio. We had very few grants that we were managing, per se, and we had put some special interest into a couple of large intervention studies. And, you know, interventions sometimes work like you would like and often times not. And I often think that the interventions are flawed because we don't spend enough time characterizing the individuals. Again, it's back to this nutrigenomic kind of mindset. Without knowledge about the genes, you could end up misinterpreting any results that you might obtain.

PC: Give me an example of a large intervention study.

JM: The two big ones that were going on when I first came in were WHEL and WINS. WINS is a Women's Intervention Nutrition Study. It was a low-fat diet, and recurrence of breast cancer. WHEL is a Women's Healthy Eating and Lifestyle intervention study, I should say. It was primarily a high carotenoid, high Vitamin-A, if you want to call it that –

PC: I'm sorry, I missed that.

JM: Vitamin A. Carotenoids is, actually, what it is, so it's more than just Vitamin A, per se, but those kinds of fruits and vegetables and a recurrence of breast cancer. So that was several million dollars that were being provided for those kinds of large intervention studies. Today, much more of the focus on that than it was on, say, some of the basic nutrition science.

PC: And at that time, we understood a lot less about genomics than we do now.

JM: Right.

PC: So I don't know. Would you say that because we know more about genomics, that the results of these studies are pretty well limited?

JM: I would. However, those investigators are even going back and looking at some gene phenomena now because they didn't start out that way. While we can have public health initiatives and recommendation, and good for the general population, it may be a sub- group who really benefits maximally. If recommendations hurt the other sub groups, is the issue. There are some strategies that actually might hurt an individual. We have some limited information that, while a certain gene polymorphism may give a benefit to 80 percent of the population, 20 percent actually may be placed at risk because of it. The classic example is that associated with heart disease. You know, part of NIH was built on what we refer to as a hyperlipoproteinemia. That means an elevation, basically, in cholesterol.

There is a sub group, it's probably about 10 to 15 percent of the population, that has what's called a type "four" hyperlipoproteinemia. A type four is carbohydrate sensitive. So if you add a lot of carbohydrates in the diet, their cholesterol goes through the roof.

Thus, if you recommend to the general public to decrease fat, what do you think goes up in the diet of these individuals? It's either protein or carbohydrates. So, by definition, that general recommendation actually places a risk – a population at increased risk. So this is, I think, an important issue. I think the same thing can happen when it comes to cancer risk, I think it can happen with heart disease, in general. It can happen with hypertension, with a bunch of other things, you know, the major killers that we worry about.

PC: And as this has evolved over time, are we eventually moving towards something like a customized diet for people?

JM: I think personalized nutrition is going to become more commonplace, absolutely. As I said earlier, I think eating is still one of the pleasures of life, and so we will have a little combination of enjoyment more and personalized from the standpoint of what nutrients we need to promote optimal health.

PC: And would the cutting edge be for those people who have had cancer, to – for example, to retard its coming back? Or would it be for people as a health preventative?

JM: Well –

PC: Not – health preventative sounds wrong. I know we use that term, but it's really a disease preventative.

JM: Well, you know, candidly, I would much rather prevent the first tumor from occurring, all right, and less emphasis on recurrence, but I think we need information about prevention and therapy. The data that comes from NCI about projections for cancer risks are going to be between now and 2050 are pretty gloomy. I mean, they're looking like a rather substantial increase. Part of that is because we're an aging society, and we're growing, at least in the obesity arena, and both of those are contributing factors. So I'd rather prevent than treat. So we are looking for strategies that you can introduce at the very beginning, based on the individual's genes, that will reduce their risk of developing a cancer. You know, in someone who is at high risk, there may be another strategy that is needed for dietary components. It may be different foods, or different compounds, different intervention times. I don't know the answers to those questions, but that's what we are pursuing.

PC: How does the office work in terms of integrating the different kinds of cancer prevention strategies?

JM: I'm not quite sure what you're saying.

PC: Well, to hear you speak, there's the nutrition part of it, there's the chemo, there's – that is, what are the chemical therapeutics or chemical things that you look at and how does the office integrate those and look at them in the total picture of cancer prevention?

JM: Wow, that's a tough one. It's, actually, even broader than what you say. I mean, it certainly is possible that you could take a food component – I mean, a classic would be a green tea extract, it's called EGCG, that if I take in more modest amounts, that's a nutritional intervention. If I use really exaggerated intakes, you know, like I would have to drink 100 cups of tea a day to get that exposure, that's really a pharmacological effect, so that's really chemo prevention and not nutrition.

PC: Uh-huh.

JM: If either of those concentrations / exposures might be an interaction with a drug, Tamoxifen or whatever drug, doesn't matter, Fluorouracil, those are things that are done. If it is done for the treatment and regression of a tumor, it actually belongs in therapy and diagnosis more than it belongs in cancer prevention. At least that's been our mindset.

We have worked with chemoprevention and those involved with therapy announcements.

PC: Work with them being –

JM: The Division of Cancer Therapy and Diagnosis.

PC: Uh-huh. Okay. Another part of NCI. We work with other units within the Division of Cancer Prevention

JM: Yeah, absolutely.

PC: Uh-huh. And but in cancer prevention, sort of a critical – well, two critical elements, it would seem to me, and you correct me here if I'm wrong, but one is to advance this information to the medical fraternity.

JM: Right.

PC: And the second is the public.

JM: That's correct.

PC: And what strategies, and how do you decide on these strategies to go from DCP to a broader audience?

JM: Yeah. Okay, so – boy, those are tough issues as well. In many ways, I think that what we do is we help the health care professional more than the lay public. What we do is we foster research that will serve as the foundation for recommendations that can come from a variety of groups to the public.

PC: Uh-huh.

JM: Our primary mission, I think, is to foster nutrition science research. However, I also think that we also need to do something with the translation of information. So we actually have a practicum, it's a week-long course, that we offer on nutrition and cancer prevention. We have people that come to NIH for this. Attendees can have a background from dieticians to a practicing physician. We, typically have around forty people that will participate in this week-long course. This we offer as one way to get the word out and promote additional research. We also have a program that's called Stars in Nutrition and Cancer, and that is a seminar series twice a year that is offered on the NIH campus to make sure that NIH is aware of cutting issues when it comes to nutrition and cancer.

Finally we are also preparing a number of fact sheets. They're aimed more at the, again, the health professional than they are the lay public, but you know, they go into our web site, and it becomes general information.

In fact, we're working on some fact sheets that are for the general public more than they are the health professional. They're written a little differently. So we do some public activities, but they are, I would say, probably 20 to 25 percent of our activities, whereas most of our attention is devoted to the basic nutrition science, including some interventions in humans.

PC: And you run those programs.

JM: Yeah. We're an extramural program, and so we work with scientists that submit grant applications to make sure that they get the best applications submitted, that they are reviewed appropriately, and then we help manage the grants after the award has been made. A lot of the work that is accomplished prior to submission is to make sure that the applicants are submitting high-quality applications. And I think that's one of the reasons we've been quite successful in increasing our grant portfolio. The other activity that we do is going on the road and to talk about some of the limitations that currently exist in understanding diet and cancer prevention inter-relationships. We also develop funding opportunity announcements and encourage applications to submit a response to the announcement.

Finally, we also participate in a little of what I would loosely call an intramural activity. That means that we work collaboratively with several federal labs to undertake nutrition intervention studies ourselves, both pre-clinically and clinically. For example, we work with the Beltsville Human Nutrition Center, and we examine some dietary intervention studies using specific foods and food components on molecular targets that are linked to cancer risk and tumor behavior.

PC: Uh-huh. And that – do I understand correctly that there's two tracks at work here. One, that you would set the agenda for the kinds of research interests that you think should be pursued; and the second is that your research – or the science community will come in and, research science community would come in with their own proposals about something that –

JM: Absolutely. There is a wandering road that everybody can come in with whatever proposal they think is most appropriate. We encourage that. That's always been an important approach to NIH. Nevertheless, we don't think we're totally brain dead, so we can actually start examining the literature and say, "Wait a second. There are gaping holes here, and this is where we need some additional information." We, in essence, put together what are called funding opportunity announcements, and they can be either a request for proposal (RFP) or request for applications (RFA). Typically this means there is set aside monies for an RFA/RFP, or they can be program announcements without set aside funds. Over the last couple of years, they've been primarily program announcements because we don't have a lot of flexible money that we can put into RFAs.

PC: And most of these funding grants will go how many years?

JM: Some go for about five years. We've had funds that were put aside for epigenetics, molecular targets, etc. There's this methylation process for DNA, there are histories, etc. that are part of the epigenetics overall process. They fine tune how DNA is read. Diet has a role in that. Overall, we were really out in the scientific community long before many, saying, "Hey, listen, we need some more cutting edge research in this area." We had some set-aside monies, and got some investigators to submit applications. We're starting to see the fruit of those activities because the results that come from those early investigations stimulate other investigators to get involved. As a result of our activities, many conferences now focus on diet and epigenetic processes.

PC: And is this selection done entirely within your branch, or is it – the branch chiefs get together and decide, with Peter, the direction of where funding should go?

JM: All of the above. The beginning of the idea starts here in the group. We kick it around, we develop what's called a concept. That concept has to be built on some logic, and so you have to build on the science that says that research should go in one direction or another. It needs to also include where we want the new research to focus, and we resent that to what's called the coordinating unit for the divisions, which includes all of the unit administrators, along with Peter. Either the concept makes it through that review or it doesn't. If it makes it through, then it goes to the executive committee at NCI for consideration. If it makes it through that and if it is a request for monies, then it goes to the Board of Scientific Advisors for their recommendation to the NCI director.

PC: Uh-huh. And does DCP have someone on that NCI panel?

JM: Peter.

PC: Okay, Peter.

JM: Yeah.

PC: All right. So you are represented. Because at times, NCI is a disease-oriented not a prevention-oriented –

JM: It's always an issue. And it's always an issue when it comes to nutrition because you actually have believers and non-believers. Probably many more non-believers. In many ways, drugs are viewed as the saving grace for cancer, not dietary intervention. You know, as I said at the beginning, 30 to 35 percent of cancers are thought to relate to dietary habits. So the numbers, while there's some consistency in finding that, there's a lot of variability. All right? And we don't understand that variability. The cynic will say, "Hey, wait a minute. We're better off just finding a drug and let people eat what they want to." For some of us, we believe that food components have multiple targets. You can get multiple benefits, you don't have to have some side effects, which often will occur with drugs, and it is the better strategy. As you just alluded to just a seconds ago maybe it's a combination of diet and drugs is really where we ought to be focusing some more of our attention.

PC: One of the things you mentioned is that you look at the literature.

JM: Uh-huh.

PC: And I notice that you and other branch chiefs have served on a number of editorial boards for the professional journals.

JM: Uh-huh.

PC: Is this something that is encouraged within the division?

JM: Absolutely. Dr. Greenwald wants us to be involved and proactive. Does he, has he ever come to me and said, "Wow, you ought to be on an editorial board"? No. He, basically, says, you know, "Be visible. Be involved." If we are, we're going to get invitations to serve on editorial boards. There's many ways that you can get the word out to the scientific community about emerging science. Serving on editorial boards is only one of those, but I think that's important. So I encourage everybody in NSRG to be on editorial boards, and many of us are!

PC: And what are the other ways to get the word out?

JM: As I said, earlier scientific participation in meetings makes presentations about nutrition research opportunities and challenges. We actually, as I said, are involved in some of our own research, and so we can present some of that science as well. We often will write what I refer to, loosely, as white papers or editorials/ reviews. They're often a synopsis of the state of the science. They get a lot of visibility as well, and that's really important.

PC: And what about working in the private sector? I noticed you're on a couple of boards, and I'm not sure what they are, but the Mushroom Council struck me as being [laughter]

—

JM: An interesting one.

PC: Yeah. [Laughter].

JM: [Laughter].

PC: I would not have expected that.

JM: Well, you know, there are some very interesting compounds that are actually found in mushrooms. I did studies with mushrooms, actually back in my old days Penn State, where you can actually demonstrate that adding selenium to the wash water increases its content in the mushroom. It can become an important source of that trace element, which has been, in some cases, identified with – higher amounts with a lower risk of certain cancers. There's some recent data, one can radiate mushrooms and increase your Vitamin D content, and that's been found by some to be a deterrent to cancer as well. There's a lot of health opportunities to explore since some really strange carbohydrates that look like they are deterrents to tumors. Again, that council is designed to examine research needs, and so it's global. I've been intrigued with some of the areas that have been presented with mushrooms and immunity, immunocompetence.

There sure looks like there's something worthwhile to consider in mushrooms. Even the aspect of incorporating mushrooms as a replacement for higher-fat types of foods and a weight reduction is surfacing. Thus, there are lots of reasons why to be involved. I can say the same about a lot of other groups like this council. This, again, is not a company, but it is more of a global type of issue when it comes to this particular food item.

PC: And I notice you were in seafood as well.

JM: SEAFOODplus, same types of issues. I'm no longer on that. One of my colleagues here in the program, Cindy Davis, is actually now part of that program.

PC: And these are – this, I take it, is another way to get the word out, but also to see what comes back?

JM: Absolutely, to find out what other people are doing in these areas, to share information about what NCI is doing or NIH is doing in these arena, and kind of help get some of these organizations to be on the same page. Even at times, to assist in and foster some collaboration.

PC: I also noticed that you have an interest in garlic.

JM: I sure do. I have for years. Yeah. Absolutely. You know, I spent, oh, probably fifteen years or so or more dealing with garlic and its ability to suppress chemically-induced or transplantable tumors, and so I think it's another one of those factors that's associated with a suppression in cancer risk and tumor behavior. We need to figure out who would really benefit most and we need to know how much garlic you really need to take in to really get a response.

PC: Uh-huh. And I take it the tea – were you in Japan for the tea?

JM: Oh, no, I was actually in there talking about nutrigenomics. This has been my focus over the last five or six years. And so I was asked to give a key note presentation on nutrigenomics at a meeting in Niigata, and then we had a visiting professor in here from the National Institutes of Health and Nutrition in Tokyo. She invited me to actually come to Tokyo to give a presentation at her meeting, and that one was, actually, on functional foods and bioethic food components in cancer prevention. So a little different presentation, but all relating to nutrition and cancer prevention.

PC: As I recall, the Japanese had some issue with whatever the coating was on sushi rice, and might've led to higher incidence of stomach cancer years ago.

JM: Well, I don't know about that. You know, the fish issue has really been the one associated with the stomach cancer that you'll get the drying, the salting, those kinds of things were associated with a higher risk of stomach cancer more than the rice, per se. Actually, we were chatting a little bit of what happens in Asians, that they have a little different gene profile that's associated with a better use of starchy items, such as would occur with starch. That comes from rice.

PC: How do you handle a situation where – I mean, you must work somewhere along the line with the FDA because some of these companies will announce that this, you know, we have a high rate of antioxidants and, therefore, blueberries are good, and there's a run on blueberries or pomegranate juice or whatever today's, you know, fad is – how does the Division of Cancer Prevention handle that?

JM: Well, let's just say it this way. We have periodic meetings with FDA to chat about topics of common interest that relate to diet, dietary supplements and health. So I'm not the only person on those calls, but I am certainly one that's involved. This is another venue that we use to talk about common interests. As well as that, we have co-sponsored workshops and conferences with a host of different federal groups. I might add that we serve as a source of the science foundation for policy. We are not the policy group.

They are the policy group. So we often chat about the state of the science and what conclusions can be made. It is up to them to make decisions as to what the science means for the general public.

PC: Uh-huh.

JM: Our fact sheets are provided to health care professionals for their use. We often have discussions about the state of a particular science. Certainly FDA is keenly interested about identifying biomarkers that would tell us something about whether you're getting a benefit or you might be placed at risk because of an intervention strategy. We have co-sponsored a meeting in that arena and we're likely going to be sponsoring another meeting shortly, to deal with vulnerable populations. So we have a nice rapport with the FDA and many other federal agencies with a nutritional component. Andy and I know each other quite well, and we've chatted.

PC: This is Andy –

JM: Von Eschenbach.

PC: Uh-huh.

JM: We've chatted often about some issues related to where nutrition is going. All right?

Again, they're looking at it from their perspective of regulatory policies. We're looking at it from the science perspective.

PC: And so they – now they get input both from you and from who else?

JM: USDA. Actually a lot of other groups. The National Academy of Sciences is often involved. NAS has their contacts as well, some of which NIH supports. Overall, we have our finger on the pulse on some of the most important issues, and we know some of the people that are involved with some of these activities. Again, there's a nice rapport, a nice dialogue that occurs between us and many groups.

PC: And how does this all filter back in relationship to funding? Basically, it all starts there, correct?

JM: That's correct. I'm not sure what you mean by "how does it filter back"?

PC: You know, you can't lobby for funding.

JM: No.

PC: But certain groups have certain professional organizations that lobby on their behalf at NIH. I don't know whether professional dietary organizations argue for more money for more science. I'm just sort of curious how that would work. Because in the end, the word has to get out that somebody needs this and it's critical, even as a public health policy.

JM: Well, yeah. That's a tough one for me to answer. As you just said, we can't lobby per se. But, however, if FDA and NCI co-sponsor a workshop or a conference, and it identifies research priorities, and we write a white paper together, which we have done, that actually helps foster the research to get the best applications submitted. Sometimes, we will develop concepts based on that dialogue that has occurred. That will get additional grants coming in. That's not going to the Hill and saying, "NIH needs more money." However, because what we do in publishing those things, other professional groups do pick up on it and say, "Hey, listen, this is an important topic. We should actually be talking to people on the Hill about we need more research in this area, we need a better definition for what's going on." That does occur. We can't do it, per se. So it's really kind of a spin-off. Invariably, NIH, NCI, have a couple of opportunities per year, several opportunities, three, four opportunities for us to come in with kind of novel concepts about these are research areas that we need, we believe need to be addressed.

PC: Come in, come in to what?

JM: To the Executive Committee of NCI.

PC: Uh-huh.

JM: And make a request for set-aside monies. As I told you, the dollars are less plentiful these days, and so there's a greater reluctance to do that. Regardless, there still are some opportunities. You just have to compete with everyone else. That's the way life is.

Competition is not bad! That means we really have to have our act together, and that's what we're always striving to do.

PC: When you go or NCI goes up on the Hill to testify, is DCP a part of that? Who does the testimony, if so?

JM: If it's a budgetary issue, it's my understanding that that is a director of NCI, and it has been discussed with the directors of the various institutes. I would not be involved in that dialogue. Now I did get a call, I'll give you an example, last year from the – Pelosi's office, in fact, saying, "You know, we're hearing about Vitamin D. We need information about Vitamin D." And so I called NCI, and I told them they had – I had gotten this request, so I gave them some information about Vitamin D. They asked me to actually come there, along with some other people, to talk about diet and health and cancer prevention. It was really Pelosi's staff rather than Pelosi herself, but that's the way life goes. So I guess it depends on the circumstance of who goes in.

PC: But you have to – do you clear it first with Peter and then with NCI?

JM: Absolutely. I couldn't go to the Hill without getting somebody to agree that this is something I should do. Yeah.

PC: And, generally, that is not withheld.

JM: That's my understanding. I mean, I think they're responsive to people's requests from the Hill. They will often go with us. That's what happened in this case, in case other issues might surface. And I will tell you, this one started with Vitamin D and it got – well, it had multiple issues by the time we ended up in the office, let's say it that way.

PC: Do you ever get grant proposals from the private sector that is outside of the university researchers?

JM: Absolutely. They're frequently done for small business mechanisms. Well, actually, they can submit from the private research as a non-academic research institution. We have small business opportunities for people that own their own little companies can submit applications for research and development dollars. We've tried to work closely with several companies to help see that that occurs. As you may be aware, NIH – in fact, I think all the federal agencies do put a certain proportion of their dollars to the side to be used to foster small business opportunities.

PC: And how successful has that program been?

JM: I don't know that I'm not the best person to answer. I think as far as I'm concerned in nutrition it's been minimally successful. In fact, not maybe successful at all. I think that's partially because it's hard to sell nutrition to get a return on investment. We don't want to foster quackery! Obviously, you've got to foster the science that is needed to market a new product. It's been more challenging for us than it has, say, for developing a new drug. Part of the problem comes down to regulatory issues and the return on investment.

PC: And when you go – you sponsor clinical trials.

JM: Right.

PC: In – I said human clinical trials.

JM: Right.

PC: And these are of the five-year variety –

JM: That's correct.

PC: — or do they last longer?

JM: Well, some will go considerably longer than that. The WHELs and WINS that I mentioned earlier were considerably longer than that. Almost about three times that long. So it really depends on the study. We can't make awards for more than five years. But assuming progress is being made, and more information is needed, then continuation is certainly possible. And, yes, we have some grants that are up in twenty years in duration. We have others that are in the first year.

PC: And do you go back, for example in the WHELs and WINS study, do you go back and re-examine the data, or find other ways to look at the data when you have a broader historical perspective than you did after five or ten years?

JM: Well, you know, again, that's an interesting question. Remember these are grants and not contracts, so the data actually still resides at the institution where the award was made, not with us. Do we go back and look at some of the older papers and kind of reinterpret them? Absolutely. But it's not limited to those larger studies. If you don't look at history, you're bound to repeat yourself, right? [Laughter]. So I think, I think we certainly do that. But I think what we also do is that we will talk to the PI's of some of those larger grants and say, "You know, there's some new evidence recently published.

Do you have any residual samples? Have you thought about such-and-such?" That's how we have an impact. Now they're doing the same thing. I mean, they're always trying to figure out are there other opportunities for using these samples to answer research (societal) questions? Are there new questions that we need to consider frequently?

PC: And where do you think the dietary issue, or dietary approach to cancer will go in the next, let's say, five years?

JM: I think we're going to have a lot more information about genomics and be able to talk a little bit more about intervention times and quantities and who will benefit most. I think the availability of genomic information is going to increase rather markedly over the next five to ten years, and that will allow us to define better who's really going to get some benefits from dietary intervention.

PC: Is there anything that we haven't covered that you'd like to talk about in terms of the office, or the changes in the office since you've been –

JM: I think that the one key thing is that diet is one of those modifiable risk factors. There are relatively few risk factors that we, as individuals, have control over. Diet is clearly one of those that is modifiable. The modification is likely not going to be a simple answer, and it certainly, in my estimation, will not work for all individuals or at all times. So we are, in essence, focusing on several dietary modifications to really have the major impact on cancer prevention.

PC: Uh-huh. It seems that there's sort of a dichotomy here as we go toward genomics and the whole issue of general public health.

JM: Right.

PC: How in the world – and there are a number of people in DCP who are public health, you know, folks as well – how do you come to grips with that distinction? Because if diet is so –

JM: So I guess you can start thinking of it as a threshold that we have to have a certain foundation, and that is the public health. Then beyond that is the personalized approach. I think both work together. I don't think, for the most part, that they are inconsistent. I think what we're talking about is a solid foundation that is built on the science and nutrition, and then knowing something about that individual, then we can intervene with whether it's broccoli or garlic or tomatoes or whatever are individual components from those foods is what we ought to be talking about.

PC: Uh-huh.

JM: And then if it is individual components, that can be as a supplement, or if it gets high enough, that could actually be a drug or chemo prevention.

PC: Okay. All right. Well, I want to thank you very much for speaking –

JM: Certainly, it's been a pleasure.

PC: Pleasure's been mine. And I'd like to take advantage, if I need to get back to you if I may.

JM: Absolutely you can. Not a problem.

PC: Great. Thank you very much.

JM: Okay. All the best. Bye-bye.

PC: Bye.

JM: Bye.

[End of Interview]